REMARKS

I. Claim Amendments

Claims 5-8 are amended to change their dependency.

Claims 9 and 10 are amended to include a polypeptide marker having an apparent molecular weight of 6880Da, support for the amendment being found in the application, considered as a whole.

II. Election of Species Requirement

It was asserted in the Office Action that the Application contains claims directed to more than one species of the generic invention and such species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

It was further asserted that claims 2, 4, 9-11 and 33-35 are generic to a plurality of disclosed patentably distinct species of "additional polypeptide markers" comprising: a polypeptide marker having an apparent molecular weight of 66800 Da; a polypeptide marker having an apparent molecular weight of 66500Da; a polypeptide marker having an apparent molecular weight of 66300 Da...and a a polypeptide marker having an apparent molecular weight of 1005 Da (claims 2 and 4)." It was further asserted that the listed species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: "...the species represent separate and distinct products which are made by materially different methods and have different modes of operation, different functions and different effects...". Office Action pages 2.

Applicants were required to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable and to identify the claims readable on the elected species. *Id.*

Applicants respectfully traverse this election of species requirement, which they understand to be a provisional election of species requirement.

Nonetheless, in order to be fully responsive to the requirement, in the event it is made final, Applicants provisionally elect, with traverse, the additional polypeptide marker having apparent molecular weight of 6880 Da. Claims 2, 4-11 and 33-35 read on this elected species.

Applicants respectfully submit that the claims relate to a single general inventive concept, and therefore do not lack unity of invention. According to the M.P.E.P. § 1850, when the U.S. Patent and Trademark Office (the "Office") considers international applications as an International Searching Authority, as an International Preliminary Examining Authority, and during the national stage as a Designated or Elected Office under 35 U.S.C. § 371, PCT Rules 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. § 111. The M.P.E.P. also explicitly states that the decision with respect to unity of invention rests with the International Searching Authority or the International Preliminary Examining Authority. *Id.*

PCT Rule 13.1 states that "the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention'). PCT Rule 13.2 elaborates on the requirement of unity of invention by stating that this requirement "shall be fulfilled" when a group of inventions is claimed in the same international application and when there is a "technical relationship among those inventions involving one or more of the same or corresponding special technical features". The term "special technical features" means "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

Applicants respectfully submit that their claims 2, 4-11 and 33-35 satisfy the unity of invention requirement at least because all of these claims are directed to methods for the

prediction of the clinical outcome, complications, and/or mortality of an individual diagnosed with colorectal cancer or of diagnosing colorectal cancer in a sample from a mammal, wherein the same polypeptide marker, having the apparent molecular weight of 3980 Da is utilized. Applicants believe and submit that such marker is the special technical feature required by PCT Rules 13.1 and 13.2.

Applicants furthermore respectfully submit that there was no unity of invention objection issued during the international examination with respect to the set of claims substantially the same as is now pending in this U.S. national phase application. Thus, since the International Preliminary Examining Authority decided there was unity of invention, it is improper for the Office to hold otherwise. For at least this additional reason, the election of species requirement is improper and must be withdrawn.

The Office rules are consistent with the above principles. Thus, 37 C.F.R. § 1.475 states, in pertinent part:

> "(b) ...a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
>
> (1) A product and a process specially adapted for the manufacture of said product; or
>
> (2) A product and process of use of said product; or
>
> (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
>
> (4) A process and an apparatus or means specifically designed for carrying out the said process; or
>
> (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
>
> (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

All of Applicants' claims are directed to substantially similar categories of inventions, a method for the prediction of the clinical outcome, complications, and/or mortality of an individual diagnosed with colorectal cancer or a method of diagnosing colorectal cancer in a sample from a mammal. Thus, Applicants' application satisfies the unity of invention requirement.

In view of the above remarks, Applicants respectfully request that the election of species requirement be withdrawn and that all claims as submitted by Applicants be examined on the merits.

In the event that the requirement is made final and in order to comply with 37 C.F.R. Section 1.143, Applicants reiterate their provisional election of the marker having apparent molecular weight of 6880 Da as the "additional polypeptide marker", and designate claims 2, 4-11 and 33-35 as reading thereon.

III. Request for Allowance

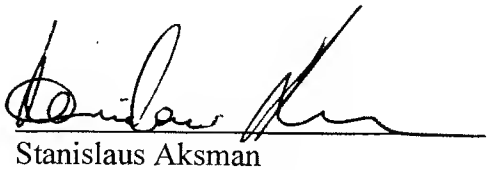
All claims are in condition for allowance an indication of which is solicited. In the event any outstanding issues remain, Applicants would appreciate the courtesy of a telephone call to the undersigned counsel to resolve such issues in an expeditious manner and place all claims in condition for allowance.

Authorization is hereby granted to charge or credit the undersigned's Deposit Account No. 50-2478 for any fees or overpayments related to the entry of this Amendment.

Respectfully submitted,

Roberts, Mlotkowski & Hobbes, P.C.

Dated: November 2, 2007

By: 

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